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APPLICATION NO.	FILING	DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/565,453	05/18	3/2006	Johann Zimmermann	ON/4-332894 9886·		
1095 NOVARTIS	7590	10/26/2007		EXAMINER		
CORPORATI		CTUAL PROPER	STONE, CHRISTOPHER R			
	TH PLAZA 104/3 OVER, NJ 07936-1080  ART UNIT			PAPER NUMBER		
2,101,111,10	Distriction and the state of th			4173		
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•			•	MAIL DATE	DELIVERY MODE	
				10/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
	10/565,453	ZIMMERMANN ET AL.					
Office Action Summary	Examiner	Art Unit					
	Christopher R. Stone	4173					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).					
Status							
1)⊠ Responsive to communication(s) filed on 18 M	ay 2006.						
	. · · · · · · · · · · · · · · · · · · ·						
3) Since this application is in condition for allowar	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.					
Disposition of Claims							
4)⊠ Claim(s) <u>1-7</u> is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) <u>1-7</u> are subject to restriction and/or ele	ection requirement.						
Application Papers							
9) The specification is objected to by the Examine	r.						
10) The drawing(s) filed on is/are: a) acce		Examiner.					
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correcti	on is required if the drawing(s) is obj	jected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.					
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:	priority under 35 U.S.C. § 119(a)	-(d) or (f).					
1. Certified copies of the priority documents	s have been received.						
	_						
3. Copies of the certified copies of the prior	• •						
application from the International Bureau	(PCT Rule 17.2(a)).	•.					
* See the attached detailed Office action for a list of	of the certified copies not receive	d.					
	•						
Attachment(s)	, <b>-</b>	(DTO 440)					
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Ll Interview Summary Paper No(s)/Mail Da						
3) Information Disclosure Statement(s) (PTO/SB/08)	5) Notice of Informal P						
Paper No(s)/Mail Date	6)						

## **DETAILED ACTION**

## Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, Applicant is required to elect a single disclosed species of formula I by defining each variable group of formula I with a particular species (a species definition like methyl, not a genus definition like alkyl) in order to specify a single compound. Applicant is additionally required to elect a single species of cat K inhibitor by defining each variable group of formula V or formula VII with a particular species (a species definition like methyl, not a genus definition like alkyl) in order to specify a single compound. Applicant is further required to elect a single disclosed disease from the list in claims 3 and 4. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Currently all claims are generic. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species are compounds with different chemical structures and properties and diseases with different mechanisms and clinical effects.

## Conclusion

Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see <a href="http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html">http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html</a>.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the

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restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed <u>on or after</u> November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed <u>before</u> November 1, 2007, the election must be filed within **ONE MONTH** or THIRTY DAYS, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file

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an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Stone whose telephone number is (571) 270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRS

Cecilia J. Tsang

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